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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,763	01/23/2004	Joseph G. Vockley	SAIC0086	3114
27510	7590	07/12/2006	EXAMINER	
KILPATRICK STOCKTON LLP 607 14TH STREET, N.W. WASHINGTON, DC 20005			AGRAWAL, RITESH	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,763

Applicant(s)

VOCKLEY ET AL.

Examiner

Ritesh Agrawal

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/11/05, 05/19/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Sequence Rules Compliance

This application contains sequence disclosures as those on pages 11, 18, and 20 of the specifications that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because each sequence is not followed by an appropriate sequence identifier. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. Applicant is reminded that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings.

Applicant is given the same response time regarding this failure to comply as that set forth to respond to this office action in which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a)

Art Unit: 1631

must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that

Art Unit: 1631

the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

The instant specification appears to claim benefit from a prior application on the first page of the specification, but the serial number of the application filed 01/23/04 is left blank. The current status of all non-provisional parent applications referenced should also be included.

Information Disclosure Statement

The Information Disclosure Statements filed on 2/11/05 and 5/19/04 have been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Specification

The attempt to incorporate subject matter into this application by reference to a utility application filed January 23rd, 2004 is ineffective because the serial number for said application is left blank.

The disclosure is objected to because of the following informalities:

The information relating to the government contract number on page one of the specification is left blank.

The title of the invention is not descriptive. The invention is drawn to methods of identifying unique genomic sequences and unique oligonucleotides, however the title does not address either of these issues. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because it is not properly formulated into a series of sentences. Correction is required. See MPEP § 608.01(b).

The use of the trademark TAQMAN has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Such usage can be found, for instance, on page 8 of the specifications.

The use of the trademark GENBANK has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Such usage can be found, for instance, on page 9 of the specifications.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Such code can be found, for example, on page 2 of the specifications. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608:01.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "selected database" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 to which claim 7 refers has both a first and a second selected database. Claim 7, as written, does not state to which (the first, second, or both selected) database(s) it refers.

Claims 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: step(s) which indicate the relatedness of the search of genomic data characteristic of a first set of organisms to the inference of unique sequences in a second set of organisms. Whereas the method is drawn to inferring sequences unique to a second set of organisms, there is no

Art Unit: 1631

mention of this second set of organisms in the method steps nor is there an explanation as to how the method steps relate to inferring these unique sequences.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Khan et al. (FEMS Microbiology Letters, Vol. 206, pages 209-214, January 10th, 2002).

The claims are drawn to a method for identifying unique genomic sequences using a BLAST search engine and the Genbank database.

Khan et al. disclose obtaining genomic data characteristic of a set, "the nucleotide sequence of the 850-bp product was determined." Furthermore, they disclose searching a genomic database using their query and a search engine to identify the sequence as being unique to two isolates of *Vibrio parahaemolyticus*, "the Genbank blast analysis did not show homology with any known *Vibrio* spp. sequences." This is disclosed within the abstract (page 209, lines 5-7), and methods (page 211, 1st

column, 2nd paragraph, lines 3-4 and lines 14-17). In explicitly describing the use of BLAST and Genbank they disclose the limitations of claims 2 and 3. While the formatting and parsing steps of claim 1 are not explicitly disclosed, appropriately formatting the raw sequence data is a prerequisite to carrying out the BLAST analysis and parsing the data (whether manually or via a computer) is required for the recognition of the uniqueness of the sequences from the BLAST results.

Claim 4 is rejected under 35 U.S.C. 102(a, e) as being anticipated by Person (US Publication # 2002/0072862).

The claim is drawn to a computer program for identifying unique genomic sequences.

Person discloses a, "computerized method for finding new unique sequences and sequence fragments," (abstract, lines 1-2) meeting the limitations of claim 4. The disclosed method includes a computer-readable medium, "a kit for analyzing nucleotide sequences comprising: an electronic medium readable by a computer," (claims 21-23), a genomic interface and formatting module, "selecting a query sequence from a redundant database [and] masking said query sequence, " (a and b of [0010]), a search interface, "comparing said masked query sequence with identified unique sequences," (c of [0010]), and a parsing method," a method for . . . analyzing the results of the comparison of the query sequence with the repeat database file and the unique database file to determine if there is one or more nucleotide sequences within the repeat database file and the unique database file that match a nucleotide sequence within the query sequence, " (c of [0011]).

Claims 5, 8, and 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al. (Bioinformatics, vol. 18, pages 1432-1437, November 1st, 2002).

The claims are drawn to a method and program for identifying unique oligonucleotide sequences.

Xu et al. disclose a method for identifying unique (termed specific) oligonucleotides and provide a computer program termed PRIMEGENES for carrying out the method. They disclose obtaining data for two bacterial species, "an application of the program using ORFs from *Shewanella onidensis* MR-1 and *Deinococcus radiodurans* R1 are presented," (page 1433, 1st column, 1st paragraph, lines 7-10). They search query sequences with a first homology search engine," PRIMEGENES first carries out the heuristic BLAST search for each ORF (query) against all other ORFs to quickly identify possible homologous sequences," (page 1433, 1st column, 2nd paragraph, lines 4-7). They divide these original queries into smaller fragments for use in primer design," PRIMEGENES selects the gene-specific fragments . . . PRIMEGENES uses a third-party software, Primer3, which takes a DNA fragment selected in the first task and designs PCR primer pairs," (page 1433, 1st column, 2nd paragraph, lines 10-11; 14-17). Furthermore, they carry out a second homology search with their target oligonucleotide sequences, "to further ensure that the primer will not amplify multiple sequences, gapless sequence alignments are carried out between the two primers and all the ORFs," (page 1433, 1st column, 2nd paragraph, lines 19-22).

While not explicitly stated, as the PRIMEGENES program represents an automatic method, the methodology of PRIMEGENES must inherently format and parse

Art Unit: 1631

data in order to carry out the homology searches and to identify homologous sequences from the searching steps.

In the absence of an explicit definition for the term combine, the term will be defined as "to possess or exhibit in combination," (dictionary.com, 2006). As such, when applied to limitations disclosed above, the PRIMEGENES program of Xu et al. discloses the limitations of claims 9-11, that is, it combines a first and second search module, a first and second parsing module, and a first and second formatting module.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. as applied to claims 5 and 8 above.

The claim is drawn to a method for identifying unique oligonucleotide sequences where a first and second similarity search engine is BLAST.

Xu et al. disclose a method for identifying unique oligonucleotide sequences using two search engines where the first is a BLAST search but Xu et al. do not disclose using a BLAST search for their second search engine.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the second search engine of Xu et al such that it was a BLAST search engine. One having ordinary skill in the art would have been motivated to use the BLAST search engine since Xu et al. clearly disclose that, "dynamic programming is slower than BLAST," (page 1433, 2nd column, 2nd paragraph, lines 7-8). Thus, by using the BLAST search engine, one could obtain the relevant data more expediently than by using dynamic programming.

Conclusion

No claim is allowed.

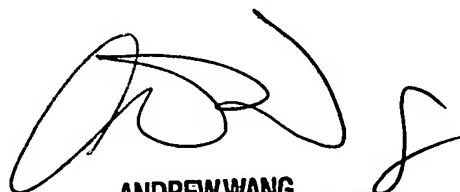
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal **RA**



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